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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/259,389	02/26/1999	KATIA GEORGOPOULOS	10287/043001	5245

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action SummaryApplication No.
09/259,389Applicant(s)
Georgopoulos, K. et al.Examiner
Joseph WeitachArt Unit
1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 27, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 10, 11, 13, 20, 21, 23, and 24 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 10, 11, 13, 20, 21, 23, and 24 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

This application filed March 26, 1999, claims benefit to provisional application 60/076,325, filed March 27, 1998.

Applicants' amendment filed November 27, 2002, paper number 23, has been received and entered. Claims 6-9, 12, 14, 17 and 22 have been canceled. Claim 1 has been amended. Claims 1-3, 5, 10, 11, 13, 20, 21, 23 and 24 are pending and currently under examination.

Response to Amendment

The supplemental signed declaration of Dr. Katia Georgopoulos under 37 CFR 1.132 filed November 27, 2002, paper number 27, is insufficient to overcome the rejection of the pending claims based upon the rejection made under 35 USC 112, first paragraph, as set forth below and in the last office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-3, 5, 10, 11, 13, 20, 21, 23 and 24 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons below and set forth in the previous office action.

Applicants summarize the basis of the rejection and note the amendment to claim 1. Pointing to the written description guidelines, Applicants argue that the amendment to claim 1 to encompass a higher degree of percent homology has met the requirements of written description (pages 4-5). Applicants note that the claim is limited structurally in that it has a specific degree of identity and functionally by setting forth specific transcription factor functions. Pointing to example 9 in the written description guidelines and noting the Federal Circuit decision in *Enzo Biochem Inc. v. Gen-Probe Inc.* Applicants argue that nucleic acids described by stringent hybridization properties may be adequately described because the conditions will recognize structurally similar nucleic acid sequences (bottom of page 6). Discussing the declaration of Dr. Georgopoulos Applicants note that the specification provides a general comparison of the Helios and Ikaros family members and provides evidence that the Helios protein functions as a transcription factor (pages 5-6). Further, it is noted that in the declaration of Dr. Georgopoulos it states that it would not be difficult to predict related functions based on the high homology of other family members (pages 7-8). Applicants argue that Examiner has overestimated the difficulty in predicting the related functions of Helios and fails to fully consider the evidence

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presented by Dr. Georgopoulos for possession of the full scope of the claims. See Applicants' amendment pages 4-8. Applicants' arguments have been fully considered and not found persuasive.

The amendment of claim 1 from 80% to 90% is noted. Further, it is acknowledged that claim 1 contains language which is both functional and structural however, the present limitations fail to meet the written description requirements for the instantly claimed polynucleotide which encodes Helios. First, with respect to the working example 9 and the discussion of the decision in *Enzo*, Examiner notes the present claims do not encompass hybridization language for identifying structurally related polynucleotides, rather only a percent identity. More specifically, wherein hybridization can be used to identify related polynucleotides from other species of animals, the present claims encompass much more than this encompassing synthetically generated sequences. Moreover, given the reliance of only a percent identity the alterations encompassed by the claim clearly would encompass in coding sequences which would not meet the functional limitations of the claims. Therefore, the recitation of a percent identity does not provide adequate description of molecules which meet any functional limitation. Further, unlike hybridization conditions used to identify other related species in nature the present claims encompass non-natural occurring sequences which clearly encompass sequences which have no function.

With respect to the functional limitations recited in the claims, initially it should be noted that the functional limitations are not directed to the polynucleotide sequence claimed, rather they

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describe functional properties of the protein encoded by the polynucleotide. The percent identity is the only structural and functional limitation of the polynucleotide instantly claimed. Be that as it may, in analyzing the functional limitations of the Helios protein encoded by the instantly claimed polynucleotide, Examiner acknowledges that the protein encoded as set forth in SEQ ID NO: 6 is a transcription factor with the limitations recited in claim 1. Additionally, it is acknowledged that the specification describes, as noted in the declaration of Dr. Georgopoulos, Helios is part of a family of highly related proteins. However, the functional limitations set forth in the instant claims are not specific to Helios, rather they are functions and/or activities which are exhibited by Helios, Aiolos and Ikaros polypeptides of the other family members. The functional limitations relied upon do not distinguish Helios from any other related family member. With respect to the comparison to other Ikaros family members as discussed by Dr. Georgopoulos, Examiner would agree that the family members share homologous domains, and that these domains would be essential for a given activity, however the comparison and arguments only describe the absence of these domains with a lack of activity. The comparisons and arguments provide guidance that molecules lacking these sequences would fall outside the functional limitations of the claims, they do not describe the essential amino acids within these domains which are required or which amino acids which can be changed without affecting the function of the respective domain. Contrary to Applicants arguments, like the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) because Helios is part of a family of highly related proteins functional limitations accorded to other

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family members would be considered adequate description (' It does not define any structural features commonly possessed by members of the genus that distinguish them from others. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.' citing *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06). In this case, the functional limitations encompass other Ikaros family members and does not distinguish Helios by any of these specific activities recited. Further, the demonstration that the absence of functionally related domains only provides guidance for what is not encompassed by the claim. The specification provides only one species of the Helios protein claimed, SEQ ID NO: 6, and is silent to any other species among the large number of species encompassed by the genus of 90% identity. Furthermore, the specification fails describe any specific alteration of any of the specific domains which would result in an functional domain, rather it relies on what is not encompassed by the claim focusing on alterations which abolish activity. 'It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.' (See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")). Accordingly, naming a type of material generally believed to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. As noted in the previous office action, Examiner would not contest that some of the variant Helios proteins besides SEQ ID NO: 6 may have the activity recited in the claim and inherent to the Helios protein, however in view of the teachings of the instant specification, the artisan would not know if any given sequence were biological

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active or maintained the recited functions absent the empirical testing of said variant protein. Given that each of the Ikaros proteins have shared biological activities, the uniqueness of each of the family members should come from their differences in amino acid sequence. Besides a general comparison, the specification fails to clearly indicate which amino acids are necessary for any given activity or which ones can be changed without consequence to the activity.

Finally, given that the functions recited and relied upon are shared among all Ikaros family members, the specification fails to provide adequate written description of the Helios gene product. As noted in the previous office action, Hahm *et al.* point out that even though work to elucidate the role of Ikaros has been done, 'the specific functions of Helios and of the Helios-Ikaros complex remain unknown' and 'remain to be elucidated' (page 792; discussion). Kelly *et al.* state [m]utational analysis of the Helios gene will help to dissect its role in regulating progenitor development in the hematopoietic system' (page 514; final paragraph), suggesting the function of Helios is not known, and that one can not relate changes in Helios expression or mutations. In light of the teaching in the present specification the invention encompasses many species of the Helios sequence and fragments which encode functional Helios protein. They include fragments of Helios, and other variants comprising deletions, substitutions, insertions, additions, or replacements of Helios sequences other than those which may naturally occur in nature. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). In the instant case, the specification provides literal support for the recited embodiments, however the specification fails to describe the relevant identifying characteristics

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of any of the nucleic acid sequences of any of the sequences which result in a Helios protein with the biological activities recited in the claims besides SEQ ID NO: 6. One cannot describe what one has not conceived. (*Fiddes v. Baird*, 30 USPQ2d 1481, 1483). In the instant case, SEQ ID NO: 6 is the single known protein to meet the biological limitations set forth in the claims, however it is unclear which other variant Helios proteins, and more specifically, what particular alterations can be made to Helios within the full breadth of the claim without empirically testing each variant.

Conclusion

No claim is allowed. The claims are free of the art of record because the art fails to teach the polynucleotide sequences which would anticipate the present claims, however the claims are subject to other rejections. Claim 2 is objected to, however would be found allowable if rewritten in independent form encompassing all the embodiments of independent claim 1.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach


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